

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

PLAINTIFFS' BRIEF IN SUPPORT OF *DAUBERT*
MOTION TO PRECLUDE OPINIONS OF
DEFENSE EXPERT JOHN FLACK, M.D., M.P.H.

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TABLE OF CONTENTS

PRELIMINARY STATEMENT.....	1
STATEMENT OF FACTS.....	2
THE <i>DAUBERT</i> STANDARD.....	6
ARGUMENT.....	8
I. Dr. Flack’s opinions that VCDs with NDMA or NDEA were equally as effective in treating hypertension as Valsartan without NDMA or NDEA have no supporting evidence and should be excluded.....	8
A. Dr. Flack admits that there is no scientific evidence to support his opinion that VCDs with NDMA or NDEA were equally as effective in treating hypertension as valsartan without NDMA or NDEA.....	8
B. Dr. Flack further tried to support his opinion with his professional treating experience, but then admitted that he has no idea which of his patients took VCDs with NDMA or NDEA or valsartan without NDMA or NDEA.....	9
II. Dr. Flack’s opinions that patients taking VCDs were not affected by the recall were based on cherry-picked evidence and should be excluded.....	10
III. Dr. Flack is unqualified to give opinions that third-party payors would have to pay for other hypertensive medications and they are not a fit for the legal theories in this litigation and should be excluded.....	12
CONCLUSION.....	13

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579, 590 (1993).....	7
<i>Elcock v. Kmart Corp.</i> , 233 F.3d 734, 746 (3d Cir. 2000).....	7
<i>Kumho Tire Co. v. Carmichael</i> , 526 U.S. 137, 152 (1999).....	7
<i>Magistrini v. One Hour Martinizing Dry Cleaning</i> , 180 F. Supp. 2d 584, 594 (D.N.J. 2002).....	7
<i>Magistrini</i> , 180 F. Supp. 2d at 594–95.....	7
<i>Padillas v. Stork-Gamco, Inc.</i> , 186 F.3d 412, 417-18 (3d Cir. 1999).....	7
<i>Paoli R.R. Yard PCB Litigation</i> , 35 F.3d 717, 742 (3d Cir. 1994).....	7
<i>Player v. Motiva Enterprises LLC</i> , No. Civ. 02–3216(RBK), 2006 WL 166452, at *6-7 (D.N.J. Jan. 20, 2006).....	10
<i>Zolof</i> , 858 F.3d at 792.....	7
<i>Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.</i> 858 F. 3d 187 (3d Cir., 2017).....	6
Other Authorities	
Federal Rules of Evidence 702.....	6
68 Fed. Appx. 356 (3d Cir. 2003).....	7

PRELIMINARY STATEMENT

John Flack, M.D., M.P.H., an internal medicine doctor who specializes in treating hypertension, was retained by Defendants and submitted a seventeen-page report for the liability phase of this litigation. Dr. Flack produced a prior expert report related to general causation and his expert opinions related to general causation were previously limited by this Court. At the liability phase of the litigation, Dr. Flack continued to give expert opinions in his expert report for which [REDACTED].

Specifically, the first half of his report mostly described his qualifications and provided a brief tutorial on medications used to treat hypertension. Next, Dr. Flack opined in his expert report that the VCDs with NDMA and/or NDEA were just as effective in treating hypertension as the valsartan medications without NDMA or NDEA and he purported to support this opinion with his own knowledge of the medical literature and his own experience with treating patients with hypertension. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This Court should bar Dr. Flack's opinions in their entirety.

STATEMENT OF FACTS

Dr. John Flack's expert report presented himself as an internal medical doctor with a specialty in treating hypertension.¹ Much of his report was filled with simple explanations of the various medications that can be prescribed to treat hypertension.² His report then attempted to explain how VCDs that include NDMA or NDEA were not worthless and how their value was still derived from its ability to treat hypertension.³ He supported this proposition by explaining that VCDs that include NDMA or NDEA were just as effective in treating hypertension as valsartan

¹ Ex. 1 (Flack's 12/19/22 Rpt.) at 3.

² Ex. 1 at 6-9.

³ Ex. 1 at 9-11.

that does not contain NDMA or NDEA.⁴ The basis for his opinion that both were equally as effective was that there is a lack of medical literature that states otherwise.⁵ Furthermore, he tried to bolster this opinion with his personal experience and suggested that he treated patients with both VCDs with NDMA or NDEA and valsartan without NDMA or NDEA and that he never observed any differences in their abilities to treat their hypertensive conditions.⁶ In effect, this opinion in Dr. Flack's report tried to go back over four years when the VCD recalls occurred to examine potential differences in patients taking hypertensive medications, but provided no support to back up this opinion other than Dr. Flack's memory.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁴ Ex. 1 at 10-11.

⁵ Ex. 2 (Flack's 2/1/23 Depo. Tr.) at 52:18-24.

⁶ Ex. 1 at 11.

⁷ Ex. 2 at 52:18-53:7, 60:21-61:5 and 63:22-64:5.

⁸ *Id.*

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Next, in his report, Dr. Flack gave the opinion that consumption of VCDs and the recalls did not affect patients with hypertension.¹⁴ He picked one statement from the FDA to suggest that the risk of taking VCDs with NDMA or NDEA was minimal.¹⁵ He then continued to explain that some patients who purchased VCDs would not have even taken the VCDs or would have been switched to another hypertension medication and that somehow these two facts taken together would show that there not even many patients who were initially prescribed VCDs that would have even been taken them by the time of the recall.¹⁶ He further explained that there were many alternatives available that patients who had their VCDs recalled could easily fill an alternative VCD and that he also observed that his patients that took VCDs did not have disruptions in finding

⁹ Ex. 2 at 44:6-48:24.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ Ex. 1 at 11-14.

¹⁵ Ex. 1 at 12.

¹⁶ Ex. 1 at 12 and 13.

hypertensive medication as a result of the recall.¹⁷ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁷ Ex. 1 at 13 and 14.

¹⁸ Ex. 2 at 12:21-13:15.

¹⁹ Ex. 2 at 24:13-17 and 26:2-20.

²⁰ Ex. 2 at 26:21-29:3.

²¹ *Id.*

²² Ex. 2 at 30:15-31:2.

²³ Ex. 2 at 44:6-48:24.

[REDACTED]

[REDACTED]

[REDACTED]

Finally, in his expert report, Dr. Flack gave the opinion that if the third-party payors had not paid for VCDs, then they would have had to pay for other medications to treat those patients' hypertension.²⁴ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

THE DAUBERT STANDARD

Federal Rules of Evidence 702 provides the standard for admissibility of expert testimony. "As a gatekeeper, courts are supposed to ensure that the testimony given to the jury is reliable and will be more informative than confusing." *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017). Additionally, "[b]oth an expert's methodology and the application of that methodology must be reviewed for reliability." *Id.* at 791. The "specific way an expert conducts such an analysis must be reliable; **'all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.'**" *Id.* at 796.

²⁴ Ex. 1 at 14-16.

²⁵ Ex. 2 at 55:10-12 and 56:6-57:2.

The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417-18 (3d Cir. 1999). An “expert’s opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation.” *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, “the expert must have ‘good grounds’ for his or her belief.” *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)).

Furthermore, “*Daubert's* gatekeeping requirement make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002), *aff'd*, 68 Fed. Appx. 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

- (i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation; (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; (iii) whether the expert has adequately accounted for alternative explanations.

Magistrini, 180 F. Supp. 2d at 594–95, internal citations omitted. To this end, the Third Circuit has affirmed the exclusion of expert testimony that “failed to consistently apply the scientific methods ... articulate[d], ... deviated from or downplayed certain well-established principles of [the] field, and ... inconsistently applied methods and standards to the data so as to support [an] a priori opinion.” *Zoloft*, 858 F.3d at 792.

ARGUMENT

I. DR. FLACK'S OPINIONS THAT VCDs WITH NDMA OR NDEA WERE EQUALLY AS EFFECTIVE IN TREATING HYPERTENSION AS VALSARTAN WITHOUT NDMA OR NDEA HAVE NO SUPPORTING EVIDENCE AND SHOULD BE EXCLUDED

Dr. Flack's report attempted to establish that VCDs with NDMA or NDEA are just as effective as treating hypertension as valsartan without NDMA or NDEA.²⁶ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] However, the proponent of an expert opinion must have evidence to support his opinion. Dr. Flack's expert opinions lack any supportive evidence, and therefore, his opinions should be excluded.

A. Dr. Flack's admits that there is no scientific evidence to support his opinion that VCDs with NDMA or NDEA were equally as effective in treating hypertension as valsartan without NDMA or NDEA

Dr. Flack spent several pages in his report explaining the various drugs that can treat hypertension.²⁹ He then made the leap that VCDs with NDMA or NDEA were equally as effective in treating hypertension as valsartan without NDMA or NDEA.³⁰ [REDACTED]

[REDACTED]

²⁶ Ex. 1 at 10-11.

²⁷ Ex. 2 at 52:18-53:7, 60:21-61:5 and 63:22-64:5.

²⁸ Ex. 1 at 11.

²⁹ Ex. 1 at 6-9.

³⁰ Ex. 1 at 10-11.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Furthermore, Dr. Flack, as the proponent of this expert opinion, must have affirmative evidence supporting his opinion, not a lack of evidence supporting the counter opinion. Without affirmative evidence, [REDACTED]

[REDACTED]

B. Dr. Flack further tried to support his opinion with his professional treating experience, but then admitted that he has no idea which of his patients took VCDs with NDMA or NDEA or valsartan without NDMA or NDEA

Recognizing that he had no scientific literature to his support his opinion that VCDs with NDMA or NDEA and valsartan without NDMA or NDEA were equally as effective in treating hypertension, Dr. Flack pivoted to his professional experience and tried to explain in his expert report that he never viewed any differences in how his patients' hypertension was treated between his patients who took VCDs with NDMA or NDEA versus his patients who took valsartan without NDMA or NDEA.³¹ [REDACTED]

³¹ Ex. 2 at 52:18-53:7, 60:21-61:5 and 63:22-64:5.

³² *Id.*

³³ Ex. 1 at 11.

[REDACTED]

Because Dr. Flack lacks any basis to support his expert opinion that VCDs with NDMA or NDEA and valsartan without NDMA or NDEA are equally as effective in treating hypertension, his expert opinion should be excluded.

II. DR. FLACK'S OPINIONS THAT PATIENTS TAKING VCDs WERE NOT AFFECTED BY THE RECALL WERE BASED ON CHERRY-PICKED EVIDENCE AND SHOULD BE EXCLUDED

Before forming expert opinion, experts should consider the body of literature surrounding those expert opinions as opposed to cherry-picking only the pieces of evidence that support the expert's pre-determined expert opinion.³⁷ However, Dr. Flack's opinions that patients taking

³⁴ Ex. 2 at 44:6-48:24.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Player v. Motiva Enterprises LLC*, No. Civ. 02-3216(RBK), 2006 WL 166452, at *6-7 (D.N.J. Jan. 20, 2006). In *Player*, this Court found the expert failed to satisfy the reliability requirement,

VCDs were not affected by the recall is based on picking only the ripest evidence that supported his position and by ignoring all other evidence, even evidence within the same documents that Dr. Flack cited. First, in his expert report, Dr. Flack cited to one sentence in an FDA document as support that the risk of ingesting VCDs is minimal.³⁸ [REDACTED]

[REDACTED] Then, Dr. Flack attempted to minimize the risk of the VCD recall by presenting a statistic that some patients who are initially prescribed hypertension medication may not actually consume that hypertension medication.⁴⁰ [REDACTED]

[REDACTED] Next, Dr. Flack cited a statistic showing that some patients who take hypertension medications will switch their medication so that the pool of patients taking valsartan would grow smaller over time as they switch from their valsartan to another medication.⁴³ [REDACTED]

[REDACTED] Finally, Dr. Flack's expert report attempted to deflect from his lack of scientific support that patients taking VCDs

as the expert failed to consider important facts without satisfactory explanation, among other things. Id. at *7.

³⁸ Ex. 1 at 12.

³⁹ Ex. 2 at 13:8-15.

⁴⁰ Ex. 1 at 12 and 13.

⁴¹ Ex. 2 at 24:13-17 and 26:2-20.

⁴² Ex. 2 at 26:21-29:3.

⁴³ Ex. 1 at 12 and 13.

⁴⁴ Ex. 2 at 30:15-31:2.

were not affected by the recall by resorting to his professional treating experience. His expert report stated that he did not witness any problems with patients who took VCDs being able to find a replacement drug after the recall, and that his experience therefore supports his opinion that patients taking VCDs did not have any problems finding replacement drugs after the recall.⁴⁵

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Finally, Dr. Flack offered no scientific evidence outside of his professional treating experience that examined whether patients had difficulties finding replacement drugs after the VCD recall.

Dr. Flack's expert opinions that patients taking VCDs were not affected by the recall should be excluded since they are entirely based on cherry-picked evidence with no methodology to examine the body of evidence surrounding these expert opinions.

III. DR. FLACK IS UNQUALIFIED TO GIVE OPINIONS THAT THIRD-PARTY PAYORS WOULD HAVE TO PAY FOR OTHER HYPERTENSIVE MEDICATIONS AND THEY ARE NOT A FIT FOR THE LEGAL THEORIES IN THIS LITIGATION AND SHOULD BE EXCLUDED

Finally, in his expert report, Dr. Flack opined that third-party payors were not affected by the VCDs since they would have had to pay for other hypertensive medications, if the patients had not purchased VCDs.⁴⁸ However, Dr. Flack is not qualified to give this opinion. [REDACTED]

[REDACTED]

⁴⁵ Ex. 1 at 13 and 14.

⁴⁶ Ex. 2 at 44:6-48:24.

⁴⁷ *Id.*

⁴⁸ Ex. 1 at 14-16.

[REDACTED]

[REDACTED]

[REDACTED] In addition, Dr. Flack's expert opinions are not a fit for plaintiff's allegations, but rather, seek to change the landscape by opining on speculative world as to what would have occurred for third-party payors in a world without VCDs. This opinion does not fit as a defense against any of the elements that plaintiffs must prove or as an affirmative defense that defendants must have affirmative proof of support. Since Dr. Flack is unqualified to give these opinions and since these opinions are not fit for the legal theories in this litigation, they should be excluded.

CONCLUSION

For the foregoing reasons, John Flack, M.D., M.P.H., should be precluded from offering his opinions related to liability in this case.

Respectfully submitted,

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⁴⁹ Ex. 2 at 55:10-12 and 56:6-57:2.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 13, 2023, a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

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